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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,022	03/22/2004	Jeffrey S. Kiel	455-024	1967

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EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,022	KIEL ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Applicant's arguments with respect to claims 1-2, and 5-21 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims :

Claims 1-2, and 5-21 are pending.

Claims 1-2, and 5-21 have been rejected.

DETAILED ACTION

Priority

1. It is noted that this application claims benefit of 60/457,431 (03/25/03) .

Drawings

2. None.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated clearly by Kiel et al (US2003/0077321).

Kiel et al discloses the conversion of one of the active pharmaceutical ingredients such as gabapentin (see page 2 ,paragraph # 0063) into its tannate salt complex (see 1 , (see page 1, paragraph # 0009). This is identical with the claim.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, and 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiel et al (US2003/0077321) in view of Chopdekar et al (U.S. 5,663,415).

Kiel et al discloses the conversion of one of the active pharmaceutical ingredients such as gabapentin (see page 2 ,paragraph # 0063) into its tannate salt complex (see 1 , (see page 1, paragraph # 0009); furthermore, the source of tannic acid is natural or synthetic (see page 1, paragraph # 0010).

[0007] The process provides the addition of the active pharmaceutical ingredients to tannic acid in the presence of a pharmaceutically acceptable liquid which generates tannate salt complexes. Without further treatment, the tannate salt complex of one or more APIs may be combined with pharmaceutically acceptable excipients such as diluents, binders, lubricants, glidants, coloring, sweetening and flavoring agent and processed into suitable solid-dosage forms. (see page 1 , paragraph , 0007).

The first step of this process is to create a tannic acid powder blend by combining an API with tannic acid in the presence of a pharmaceutically acceptable liquid. An anti-clumping agent also may be added to the mix. The presence of the anti-clumping agent prevents the aggregation of the tannate salt complex formed and promotes uniformity in the powder blend.

(see page 1, paragraph # 0009).

[0075] The salts of the active ingredients are preferably dissolved in purified water. However, other pharmaceutically acceptable liquids can be substituted for water such as isopropyl alcohol, ethanol, glycerin, propylene glycol, mineral oil or mixtures thereof. This leads to the dissociation of the salt into its free-base and conjugate acid forms.

(see page 2, paragraph # 0075).

In addition, the example 1 shows the preparation of a dosage form with one active pharmaceutical ingredient below:

EXAMPLE 1

[0077]

Preparation Of A Dosage Form With One API:

Ingredient	Amount (g)
diphenhydramine HCl	12.500
tannic acid	32.813
purified water	12.5 mL

(see page 2, paragraph # 0077). From this , the weight ratio of diphenhydramine to tannic acid used is 1: 3 (see 3 , paragraph #0078); the weight % of the tannic acid calculated is 56 % (32.8/57.8) based on the total mixture.

The instant invention, however, differs from the prior art reference in that the claimed reaction temperature range (15 to 150 ^{0} C) is not disclosed ; the claimed pH is between 2 to 11.

Chopdekar et al discloses a process of preparing antihistamine tannates ; for example , diphenhydramine tannate can be obtained from reacting an antihistamine selected from the group consisting of diphenhydramine, phenylephrine, pyrilamine, and etc. (see col. 3 ,lines 1-4) with tannic acid at the reaction temperature of 65 to 70^{0} C (see col. 4 ,lines 1-2) in the presence of water (50 wt %) (see col. 4 , example 2) for a period of time in the range of 5 minutes to 4 hours, thereby obtaining the resultant product by freeze-drying (see col. 3 ,lines 11-12) at a reduced pressure (see col. 2 ,lines 28-34) or under vacuum at a temperature of 60^{0} C. (see col. 4 , lines 15-17).

With respect to the unspecified ranges of pH, the limitation of a process with respect to ranges of pH, time , and temperature does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Furthermore, the selection of ranges of pH is not a patentable modification in the absence of unobvious results. In re Rose, 105 U.S.P.Q. 237 (C.C.P.A. 1955). The pH value is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control the reaction process.

Kiel et al expressly discloses the conversion of the active pharmaceutical ingredients such as diphenhydramine, phenylephrine, pyrilamine, gabapentin (see page 2 ,paragraphs # ,0016, 0019,0028, 0063) into its tannate salt complex (see 1 , (see page 1, paragraph # 0009); furthermore, the source of tannic acid is natural or synthetic (see page 1, paragraph # 0010). Similarly,Chopdekar et al does teach the process of preparing pure antihistamine tannate compositions by reacting an antihistamine selected from the group consisting of diphenhydramine ,phenylephrine, pyrilamine, and etc. with tannic acid at the reaction temperature of 65 to 70^0 C in the presence of water ,thereby obtaining the resultant product at a reduced pressure or under vacuum. By comparison, there is an equivalency among diphenhydramine tannate, phenylephrine tannate,and gabapentin tannate with respect to preparing the their corresponding tannate pharmaceutical forms between the prior art.

Therefore, if the skilled artisan had desired to convert the active gabapentin pharmaceutical ingredient into its tannate salt complex as an alternative to the diphenhydramine tannate composition, one skilled in the art would be motivated to incorporate Chopdekar's et al teaching of preparing the tannate composition into the Kiel et al process. This is because the skilled artisan in the art would expect such a combination to be successful in producing gabapentin tannate as the guidance shown in both prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** 9/22/05